13. VACCINE STORAGE UNITS

The following information outlines the storage unit requirements of the Montana VFC Program.

General Requirements

Refrigerators and freezers used for storing VFC vaccine must:

- Maintain required vaccine storage temperatures year-round:
  - Refrigerator: 35° to 46°F (2° to 8°C)
  - Freezer: 5°F or colder (-15°C or colder)
- Hold the year's largest inventory plus ice packs (freezer) and water bottles (refrigerator) to stabilize temperatures
- In each unit have a working National Institute for Standards and Testing (NIST)- or American Society for Testing and Materials (ASTM)-calibrated thermometer that complies with the Montana VFC Program thermometer policy (See Section 14)
- Be dedicated to vaccine storage (Food and beverages are not allowed in vaccine storage units.)
- Not be a dormitory-style appliance (see section below).
- After October 1, 2013, new or replacement units cannot be combination units where both the refrigerator and freezer are used to store VFC vaccine (See *Combined vs. Stand Alone Units* section below).

Dormitory-Style Storage Units are Prohibited

Dormitory-style (also called "bar-style") refrigerator/freezer units are those where the freezer is contained within the refrigerator, and both are accessed by one external door. Please note that the term "dormitory-style" does not refer to the size of the unit. It refers to the location of the freezer within the refrigerator compartment. These units cannot reliably maintain vaccine storage temperatures.

The CDC and the Montana Immunization Program prohibit the use of dormitory-style storage units for storing VFC vaccine.

Figure 1 Dormitory-Style Refrigerator/Freezer

During the re-enrollment process each year, VFC providers must certify that they do not use dormitory-style storage units to store VFC vaccine.

Combined vs. Stand-Alone Units

Definitions:

- Combined units have a refrigerator and freezer compartment in one appliance.

- Stand-alone units have just one compartment that is either a refrigerator or freezer.

Currently, only varicella-containing vaccines require frozen storage. If you do not administer varicella-containing vaccines at your facility then you do not need a freezer for vaccine storage.

The CDC-recommended best practice for vaccine storage is to use stand-alone refrigerators and freezers. This can be accomplished using a stand-alone refrigerator and stand-alone freezer or by using just the refrigerator in a combined unit and a stand-alone freezer. If freezer storage is not required, you can just use the refrigerator in a combined unit. The combined units cannot be dormitory-style.

Starting October 1, 2013, the Montana Immunization Program prohibits VFC providers from acquiring new or replacement storage units that are combined refrigerator/freezers where both compartments will be used to store vaccine. Providers currently using the refrigerator and freezer in a combined unit can continue to do so as long the units have been approved by the Immunization Program (see *Storage Unit Approval*, page 49) and the data loggers show that they reliably hold vaccine storage temperatures. However, if you are a new provider or are obtaining new or replacement equipment, you must follow the recommended best practice and obtain stand-alone units.

Combined units regulate temperature by sharing cooled air between the refrigerator and freezer compartments. This makes temperature regulation in both compartments difficult. Please be aware of the following issues when using combined refrigerator/freezers for vaccine storage:

- Avoid units with a single control for both the refrigerator and the freezer. This configuration makes it difficult to maintain appropriate temperatures in both compartments and increases the likelihood of freezing vaccine in the refrigerator.
- Never place vaccine or thermometers (i.e., data loggers) near vents and fans in the refrigerator. These areas may be markedly cooler than the rest of the compartment (even freezing!).
- When making adjustments in one compartment, always carefully monitor temperatures in both compartments. This is especially true when adjusting the freezer as this could cause the refrigerator to drop below freezing.

Domestic Grade vs. Pharmaceutical Grade

Domestic (or "household") quality storage units are those typically found in homes and sold at retail appliance stores. The Montana Immunization Program allows the use of domestic-grade appliances to store VFC vaccine as long as combined refrigerator/freezer units have a separate external door for the refrigerator and freezer compartments and are not dormitory-style units (See *Dormitory-Style Units* above).

Laboratory- or pharmacy-grade refers to storage units that are specifically designed to store vaccine and pharmaceuticals in a laboratory or pharmacy setting. These are the highest quality option for storing vaccine. Laboratory-grade appliances come with safety, temperature control, and security options typically not found on domestic units. Although usually more expensive, they come in a wide variety of sizes, configurations, and prices, including moderately priced under-counter models ideally suited for small clinics.

Freezers – Frost-free vs. Manual Defrost

The Montana Immunization Program allows both frost-free (automatic defrost) and manual defrost freezers for vaccine storage. Definitions:

- Frost-free units cycle to a warmer temperature roughly once every 24 hours to melt ice off the inside of the freezer compartment.
- Manual defrost units do not have a "defrost cycle" and accumulate ice on the inside of the compartment. They require periodic manual defrosting to melt the ice.

There are disadvantages to both defrost scenarios and facilities must decide which feature best fits their situation:

- The temperature cycling parameters in frost-free units must meet Merck specifications (contact the Immunization Program for details).
- Also for frost-free units, temperature monitoring equipment (i.e., data loggers) must be adjusted so the out-of-range alarm is not triggered with each defrost cycle (See the current Data Logger Instruction Manual).
- Manual defrost units typically hold vaccine storage temperatures steady and do not routinely cycle out-of-range, but alternate vaccine storage and temperature tracking must be arranged while you defrost your appliance.

Other Recommended Features:

- Fully adjustable shelves
- Door locks
- Door ajar alarm
- Battery back-up

Size Determination

Your VFC vaccine storage unit must be able to store the year's largest supply of vaccine including ice packs and water bottles used to stabilize temperatures. It also must be large enough to allow spacing between vaccine packages for proper air circulation (See Vaccine Placement, page 51).

To determine the size storage unit you need, calculate the largest number of doses you will have on hand during the year for both your refrigerator and freezer. Be sure to include seasonal influenza and private stock if it will all be stored in the same unit. Multiply the maximum doses by 1.25 to account for package spacing. Use this number (maximum doses) and the chart below to determine the minimum cubic feet of storage space you will need.

Table 1 Recommended Minimum Cubic Feet of Storage Space Based on Maximum Doses

Refrigerator		Freezer	
Maximum Doses	**Minimum Cubic Feet Required**	**Maximum Doses**	**Minimum Cubic Feet Required**
1001–2000	40	501–600	7–14.8
900–1000	36	201–500	5–5.6

Refrigerator		Freezer	
Maximum Doses	**Minimum Cubic Feet Required**	**Maximum Doses**	**Minimum Cubic Feet Required**
801–900	21–23	0–200	3.5–4.9
701–800	17–19.5		
401–700	11–16.7		
100–400	4.9–6.1		

Setting Up your Storage Unit

Follow the procedures below when acquiring a new storage unit, moving an existing unit, or reestablishing a unit after a power outage or repair.

Unit Placement

- Place the unit close to a reliable electrical outlet (See *Electrical Supply* below).
- For proper cooling and heat exchange, locate the storage unit in a well-ventilated space away from direct sunlight and with 4 inches between the unit and surrounding walls, cabinets, and appliances.
- Do not block the motor compartment, which is usually located on the back or side of the unit.

Electrical Supply

- Place the storage unit near enough to an outlet so that the cord is not a tripping hazard and an extension cord is not necessary.
- Make sure the outlet is not controlled by a light switch.
- Place a “DO NOT UNPLUG” sign next to the outlet ***and its controlling circuit breaker***. If these are not accessible or visible, place the sign as near as possible so that anyone accessing the outlet or circuit breaker is likely to see it.
- If possible, do not plug more than one appliance into the outlet to avoid tripping the circuit breaker.
- If you have a backup power supply for your facility, make sure it is in working order, tested regularly, and that your storage units are connected to the system.
- If you do not have a backup power supply, arrange at least one alternate vaccine storage location that has proper refrigerator and freezer units, temperature monitoring capability, and backup power where your vaccine can be moved in the event of a power outage. Record this information in Section 12 of this document.

Temperature Stabilizing

- Plug the unit into the electrical outlet and set the temperature to fall within the following ranges:

  Refrigerator: 35° to 46°F (2° to 8°C)

  Freezer: 5°F or colder (-15°C or colder)

- If the unit has a thermostat, set to the following target temperatures:

  Refrigerator: 40°F or 4°C

  Freezer: -5°F or -20°C

- If the unit has a controller with numbers or words (e.g., “colder”), set as follows:

  Refrigerator: Set slightly warmer than mid-range.

  Freezer: Set to mid-range.

Please note – For most numbered temperature dials, the higher the number the colder the temperature. Check your owner’s manual to avoid improper adjustments.

- Place a working program-compliant thermometer (data logger) inside each storage compartment in a central location near vaccine but away from walls, vents, fans, and cooling coils. The Montana Immunization Program supplies data loggers to VFC providers (see Section 14).
- Place several containers of water along the inside walls, in door racks, and vegetable bins (“crispers”) of the refrigerator, and several frozen packs along the walls and in the door rack of the freezer. These will help stabilize temperatures when the door is open and in the event of a power outage. Do not impede air flow by over-filling with water bottles and ice packs.
- Make sure doors close tightly and seals are intact.
- Allow the unit to stabilize overnight and check temperatures in the morning.
- Adjust the dial or thermostat until the target temperature is achieved and held for at least one week. Log temperatures at least twice a day and download data logger data as needed during the adjustment period (See Data Logger Instruction Manual).

Storage Unit Approval

The Immunization Program must approve all storage units and thermometers used to store and monitor VFC vaccine. To have a storage unit/thermometer approved, providers must submit:

- One week of temperature (data logger) data (See Section 14 and your Data Logger Instruction Manual for details)
- One week of paper temperature logs
- Storage unit make/model information.

This requirement applies to:

- New VFC providers
- Providers setting up a new VFC storage unit
- Providers reinstating a VFC storage unit after a repair
- Providers commissioning a new Data Logger or other program-compliant thermometer.

The Immunization Program reviews your temperature data and determines whether your storage unit and thermometers are ready for vaccine. Do not use the storage unit until it has been approved by the Immunization Program.

Vaccine Placement

- Place vaccine in the middle of the compartment away from ceilings, walls, vents, fans, coils, and cooling plates (stand-alone refrigerators). In the refrigerator compartment of combined units, keep vaccine away from vents or fans channeling air from the freezer.
- Never store vaccine in door racks or vegetable bins (i.e., "crispers"). Consider removing vegetable bins to facilitate air circulation. This will provide more space for water containers.
- Clearly label vaccine "VFC" and keep it physically separated from private stock.
- Keep vaccine in its original packaging and organize by vaccine type. Consider physically separating vaccines with similar names, packaging, or antigens to avoid administration errors.
- Check expiration dates on a weekly basis and organize packages so that short-dated vaccine is used first (record your process in Section 12).
- If containers are used to organize vaccine, use only open (no lid) containers that allow air to circulate, such as wire baskets or cardboard boxes.
- Never store food or beverages in vaccine storage units. Other biologicals can be stored in vaccine storage units as long as they are physically separated from vaccine to prevent contamination and administration errors.
- Diluent packaged with the vaccine should be stored at the same temperature as the vaccine. Diluent packaged separately from the vaccine can be stored refrigerated or at room temperatures.

Routine Temperature Monitoring

- VFC providers are required to monitor and log temperatures on VFC vaccine storage units as described below. Providers must use the paper log forms provided by the Immunization Program (available on our website at www.immunization.mt.gov). This is required even when your unit has a continuous monitoring chart or data logger, or a temperature alarm (Please refer to the Data Logger Instruction Manual and Section 14 for more information on data loggers).
  - Record current temperatures twice per day, morning and evening by putting an "X" in the box next to the appropriate temperature.
  - Record minimum/maximum temperatures once per day in the morning by putting an "M" in the box next to the appropriate temperatures.
  - Record the status of the data logger LED light by putting a "Y" for yes or "N" for no in the appropriate box of the "LED Green" row.
  - Respond immediately to red warning lights or out-of-range temperatures.
- Do not make temperature adjustments without informing your Vaccine Manager or Alternate Vaccine Manager. Consider posting a sign discouraging temperature adjustments by unauthorized personnel.
- DO NOT adjust temperatures in the evening or before a weekend when temperatures cannot be monitored.
- When adjusting temperatures, make slight changes to the thermostat or temperature dial and allow the unit to stabilize for 30 minutes. (Check your owner's manual to make sure controller adjustments are in the proper direction.) Check and record the temperature. Repeat, until the temperature is comfortably within range and stable.

- Record all temperature adjustments and issues with your storage unit on a Vaccine Storage Trouble-Shooting Log (page 3 of the State-supplied temperature logs). Logging these events will communicate vaccine storage issues to all staff, and document recurring events before they lead to major vaccine loss.
- Be proactive in addressing storage unit issues before they result in vaccine wastage or patient recall situations.

Out-of-Range Temperatures

- VFC providers must take action if:
  - They register a red warning light on their data logger or out-of-range indication if using other compliant thermometers.
  - They record a current or min/max out-of-range temperature on their temperature logs.
- Providers experiencing the out-of-range temperature indications listed above should immediately obtain a Vaccine Incident Report from www.immunization.mt.gov and follow steps 1–6 on the report. Then call or email the Immunization Program immediately–444-5580 or hhsiz@mt.gov. Do not complete the entire Vaccine Incident Report until you have consulted with the Immunization Program.
- All temperature excursions must be documented either through a completed and submitted Vaccine Incident Report or an entry in the Vaccine Storage Unit Trouble-shooting Log (third page of paper temperature log), depending on the circumstances and guidance from the Immunization Program.